



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/675,107	09/30/2003	Michael A. Wack	DEP-673CIP2	4990

27777 7590 11/13/2008
PHILIP S. JOHNSON
JOHNSON & JOHNSON
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003

EXAMINER

RAMANA, ANURADHA

ART UNIT	PAPER NUMBER
----------	--------------

3775

MAIL DATE	DELIVERY MODE
-----------	---------------

11/13/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/675,107	Applicant(s) WACK ET AL.	
	Examiner Anu Ramana	Art Unit 3775	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 August 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-28 and 32-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-28 and 32-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 1/22/08 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 32 is rejected under 35 U.S.C. 102(e) as being anticipated by Aikins et al. (US 2003/0040748 A1).

Aikins et al. disclose a guide including: a body having a riser 170; a first targeting guide 196; and a sheath 202 fittable to the body. Aikins et al. further disclose a compression drill guide 204 slidably fittable within the elongate bore of the sheath; and a noncompression drill guide or tap sleeve slidably fittable within the elongate bore of the sheath (Figs. 18 and 21 and paras [0076]-[0078]).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 19 and 21-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Herzenberg et al. (US 5,403,322) in view of Miller (US 2,424,485).

Herzenberg et al. disclose a guide including: a body having a riser 12c; a first targeting guide 11; a drill sleeve or tube 46 capable of being fitted to the body; and a sleeve or bushing 56 received in the tube wherein the external surface 56 of bushing is

Art Unit: 3775

sized and shaped to fit in the bore 52 of tube 46 (Figs. 1 and 8-10, col. 4, lines 30-68, cols. 5-7 and col. 8, lines 1-13).

Herzenberg et al. disclose all elements of the claimed invention except for a tube having an elongate bore with a non-circular transverse cross section.

Miller teaches tapering the external surface of a bushing and tapering the bore 8 of the liner or sleeve in which the bushing is received to provide a tight fit between the bushing and the liner (Fig. 2 and col. 2, lines 18-48).

It would have been obvious to one of ordinary skill in the art to taper the internal surface of the bore of Herzenberg et al. tube to provide a tight fit with the bushing received in the tube as taught by Miller. Using the known technique of providing a taper to the inner bore of the Herzenberg et al. tube, or providing a non-circular transverse cross section would have been obvious to one of ordinary skill.

Regarding claim 21, Herzenberg et al. disclose their guide to have a radiolucent body (col. 3, lines 47-52).

Regarding claim 22, bushing 56 has a threaded portion 47 (col. 7, lines 28-36).

Regarding claim 23, bushing 56 has teeth or bushing protrusions 64 (col. 7, lines 25-27).

Regarding claim 24, tube 46 has a tube locating feature or knob 50 and bushing 56 has a bushing location feature or knob 60 (col. 7, 37-55).

Regarding claim 25, although the combination of Herzenberg et al. and Miller does not disclose a plurality of bushings, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided a plurality of bushings, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

Regarding claim 28, Herzenberg et al. disclose providing a kit including a first targeting guide 11 and a second targeting guide 40 (col. 5, lines 52-59).

Claims 19, 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over McLaughlin et al. (US 5,312,409) in view of Cartwright et al. (US 5,192,293).

McLaughlin discloses a guide including: a body having a riser 2 and a first targeting guide 4; and a tube or first bushing fittable in guide 4 wherein the bushing may be of different shapes and sizes depending on the shape and size of the drill bit being used in the surgical operation (Figs. 1 and 2 and col. 3, lines 15-25).

Regarding claim 25, the Examiner is interpreting a second bushing of a different size from the first bushing to be the alignment fastener bushing.

McLaughlin discloses all elements of the claimed invention except for the bushing to have an elongated bore with a non-circular cross section.

Cartwright et al. teach providing various adapter inserts or bushings for a drill guide or tube wherein the adapter inserts are configured to closely conform to the drill nose. Cartwright et al. also teach an adapter insert or bushing having an elongated bore that is tapered or has a non-circular transverse cross section for use with a specific drill nose (col. 3, lines 3-26).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a bushing having a non-circular transverse cross section in the McLaughlin et al. device, as taught by Cartwright et al., so that the bushing closely conforms to the shape of the drill nose.

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over McLaughlin et al. (US 5,312,409) in view of Cartwright et al. (US 5,192,293), further in view of Levy (US 5,540,695).

The combination of McLaughlin et al. and Cartwright et al. discloses all elements of the claimed invention except for a portion of the guide being made of a radiolucent material.

Levy teaches making a drill guide of a radiolucent material so that fluoroscopy can be utilized to align the drill guide (col. 6, lines 39-46).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have constructed a portion of the guide of the combination of McLaughlin et al. and Cartwright et al., for example the bushing, of radiolucent material, as taught by Levy, so that fluoroscopy can be used to check alignment of the guide.

Claims 19-20, 25-27 and 33-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aikins et al. (US 2003/0040748 A1) in view of Cartwright et al. (US 5,192,293), further in view of Miller (US 2,424,485).

Aikins et al. disclose all elements of the claimed invention except for the elongate bores of the sheath or tube, compression drill guide or first bushing and noncompression drill guide or alignment fastener bushing or second bushing to have non-circular transverse cross sections.

Cartwright et al. teach providing various adapter inserts or bushings for a drill guide or tube wherein the adapter inserts are configured to closely conform to the drill nose. Cartwright et al. also teach an adapter insert or bushing having an elongated bore that is tapered or has a non-circular transverse or oval transverse cross section for use with a specific drill nose (col. 3, lines 3-26).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a bushing having a non-circular or oval transverse cross section to the elongated bore of the Aikins et al. compression drill guide or noncompression drill guide, as taught by Cartwright et al., so that the drill guide or bushing closely conforms to the shape of the drill nose.

The combination of Aikins et al. and Cartwright et al. disclose all elements of the claimed invention except for the sheath or tube to have an elongate bore with a non-circular transverse cross section.

Art Unit: 3775

Miller teaches tapering the external surface of a bushing and tapering the bore 8 of the liner or sleeve or tube in which the bushing is received to provide a tight fit between the bushing and the liner (Fig. 2 and col. 2, lines 18-48).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have tapered the internal walls of the bore in the sheath of the device of the combination of Aikins et al. and Cartwright et al. to provide a tight fit with the bushing received in the tube as taught by Miller. Using the known technique of providing a taper to the inner bore of the sleeve of the combination of Aikins et al. and Cartwright et al., or providing a non-circular or oval transverse cross section would have been obvious to one of ordinary skill.

Regarding claims 35 and 36, Miller teaches providing an eccentric bore 13 in a bushing so that minute adjustments to the position of the drilled hole are possible (Fig. 6 and col. 3, lines 32-36).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided eccentric bores to each of the compression drill guide or first bushing and the noncompression drill guide or second bushing, respectively, in the device of the combination of Aikins et al. and Cartwright et al., as taught by Miller, to enable minute adjustments to the position of the drilled hole.

Regarding claim 37, Miller teaches providing a knurled shoulder flange 12 or visualization guide on a bushing to enable gripping and maneuvering of the bushing with respect to the liner or sleeve or sheath or tube in which the bushing is received (col. 2, lines 36-48).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a knurled shoulder flange or visualization guide to the compression drill guide or first bushing and the noncompression drill guide or second bushing in the device of the combination of Aikins et al. and Cartwright et al., as taught by Miller, to enable gripping and maneuverability of the bushing with respect to the liner or sheath or tube.

Response to Arguments

Applicant's arguments submitted under "REMARKS" in the response filed on August 1, 2008 have been considered but are not persuasive for the following reasons.

Regarding the rejection of claim 32 under 35 USC 102(e) over Aikins et al., the various elements of Applicant's claimed invention have been explained in the rejection. It is noted that the law of anticipation does not require that the reference "teach" what the subject patent teaches, but rather it is only necessary that the claims under attack "read on" something in the reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from the prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

It is the Examiner's position that since the compression drill guide is a different element than the tap sleeve, the claim limitation, "position of bore of the compression drill guide with respect to the longitudinal axis of the compression drill guide is different from the position of the bore of the noncompression drill guide with respect to the central longitudinal axis of the noncompression drill guide" is met by Aikins et al.

Regarding the rejections of claims 19 and 21-28 under 35 USC 103(a) over Herzenberg et al. in view of Miller, Applicant's arguments are not persuasive because the limitation "transverse cross section" does not imply a cross section only along a line A (page 9 of Applicant's "REMARKS"). Using broadest reasonable interpretation of claim terminology, the limitation "transverse cross section" includes a cross section wherein line A could be inclined with respect to the longitudinal axis of the shape, in which case the transverse cross section would be noncircular.

Applicant's arguments with respect to the rejections of claims 19 and 26-27 under 35 USC 103(a) over McLaughlin et al. in view of Cartwright et al. are not persuasive for the same reason as discussed above.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anu Ramana whose telephone number is (571) 272-4718. The examiner can normally be reached Monday through Friday between 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached at (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3775

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AR
November 9, 2008

/Anu Ramana/
Primary Examiner, Art Unit 3775